VAMHCS Research Service

PI TOOL FOR DEVELOPING A "VA-UM COLLABORATIVE PROTOCOL"
(To be used in conjunction with "Guidance for Developing a VA-UM Collaborative Protocol")

Investigators holding dual-appointments[1] with the University of Maryland and the VA Maryland Health Care System (VAMHCS) are required to clearly separate VA (VAMHCS) research from affiliate (UM) research. This is a requirement from VHA Office of Research Oversight.[2]

This may entail designing protocols so that there are two separate protocols (one for UM activities and one for VA activities) or designing a single protocol that clearly defines the research activities that are conducted on VA *v.* UM time, resources, etc.

To assist in this effort, please read carefully and follow the instructions provided in the "Guidance for Developing a VA-UM Collaborative Protocol". Then carefully complete the CICERO application and the "PI Tool for Developing a VA-UM Collaborative Protocol" below. **The PI Tool must be uploaded into "Additional Documents" of CICERO.**

Additionally, you should also contact the Research Service for assistance in completing this tool and the CICERO application.

PI: _____

Protocol Title: _____

IRB #: _____

DECISION TREE (please circle your answers):

a. PI has a dual appointment with the University.	YES NO
IF NO, STOP HERE.	
b. The study will be conducted completely at the VA, on VA time, using only VA resources	YES NO
IF YES, STOP HERE. This is not a VA-UM collaborative study. Submit your protocol to the IRB and then to the VAMHCS R&D Committee.	
c. The study will be conducted completely at the UM, on UM time, using only UM resources.	YES NO
IF YES, STOP HERE. This is not a VA study.	
d. For all other studies, proceed with applicable sections of the template below.	
Upload the completed PI Tool into CICERO as an "Additional Document".	

[1] Currently most VAMHCS principal investigators must hold a full-time University of Maryland Baltimore faculty appointment unless this requirement has been waived by the University Institutional Official (IO). Some PIs on VA Central IRB studies do not have UM appointments.

[2] IMPLEMENTATION UPDATE ON July 2011 Interim Guidance on Research Data Disclosures for "Collaborative" Studies December 12, 2011

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1. Research related procedures

1. Describe all research activities and locations (some specific topics are covered later in this template). If this has been done in CICERO, state the section(s) of CICERO below. If you have supplemental information, state it below. If you have developed an 'activities-locations' table(s), state this below and upload the table(s) into CICERO.

2. Recruitment

1. Clearly define what recruitment procedures & strategies is done at/through the VA v. at UM.
2. Do your recruitment letter(s) clearly describe applicable VA v. UM elements?
3. Do your advertisement(s) clearly describe applicable VA v. UM elements?

3. Data Collection, storage, use, disclosures

1. Complete the ISO/PO checklist and upload it into additional Docs in CICERO
2. Describe all data collection activities for the VA research[3] to be included in the "collaborative" study (including location of collection and storage, access and use, statistical analyses, and security measures). *If this has been done in the "Procedures" or other sections of this template or in CICERO, simply state the location*. You do not need to re-write the information here.

[3] *VA research is research conducted by VA investigators (serving on compensated, without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.* (VHA Handbook 1200.01 §3.b)

3. If VA data will be combined with non-VA data, describe when and how this will occur and where the combined data will be stored.[4]

4. Local Data Coordinating Center

1. For data that is combined, which site is the "Coordinating Center"? (Circle one)
   VAMHCS **UM** **Other affiliated site:**

2. If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data collected? (This answer may overlap with "Research Related Procedures" above. If so, please refer to that section.)

3. If the VAMHCS is the Local Coordinating Center holding the "combined data", how is the data received and combined with the UM data?

4. If the UM is the Coordinating Center holding the "combined data", will you only use the combined data set ***while not on VA time*** or will you obtain approval from VA ORD/Regional Counsel to do this as an "off-site" VA research activity?[5]

5. Study team members

[4] If the combined data are located at the non-VA site, investigators with dual appointments should not use the combined data while on VA time unless approved as an "off-site" VA research activity in consultation with ORD and Regional Counsel.

[5] In practical terms, if you wish to designate the UM as the local coordinating center, you should be prepared to provide documentation of your non-VA time. It is unclear how quickly a decision from VA ORD and Regional Counsel can be obtained.

1. How will you document which study team members (or roles) are VA-paid employees / WOCs?

2. How will you document how VA and NON-VA activities of **dual-appointment personnel** are distinguished?*

*Consider how you will document when team members on VA time will conduct activity at the UM (including data analysis), how you will document when VA employees will conduct activity at the UM while on UM time. (A general description is adequate.)

6. Locations of visits, clinics, labs, etc.

1. VA locations where specific activities will be conducted (labs, clinics, other visits, etc)

Activity	Location

2. NON-VA locations where specific activities will be conducted (labs, clinics, other visits, etc) by team members **on VA time**.

Activity	Location

3. NON-VA locations where specific activities will be conducted (labs, clinics, other visits, etc) by team members **on UM time**.

Activity	Location

7. Dispensing of study drug

1. Will study articles be dispensed through the VAMHC Investigational Drug Service (required if investigational drugs are part of the study).

8. Tissue/specimen banking

1. Will tissue/specimens be destroyed at the end of the study or will it be retained for future use[6]?

2. Where will tissue/specimens be stored during the study?

3. Where will tissue/specimens be stored for future use?

9. VA Cooperative Research & Development Agreement (CRADA)

1. Is this study sponsored by industry or by NIH (>50%)?[7]

Continuing review

1. For existing protocols in which VA data have already been combined with non-VA data at the time of continuing review, describe where the combined data are located.
2. Amend the ICF to add relevant information regarding the combined data.
3. Amend the HIPAA authorization to add relevant information regarding the use and disclosure of combined data.

[6] If samples are destroyed at the end of the study the VA does not consider the samples to be "banked". If samples are to be stored for future use, they a "bank" that needs to comply w VA requirements. If samples are returned to the VA investigator for storage at the VA, the bank is in compliance with VA. VA Tissue Banking Program: http://www.research.va.gov/programs/tissue_banking/

[7] If YES, a CRADA is required. Begin this process with the Executive Director of the Baltimore Research & Education Foundation (BREF), David Johnson, PhD, 410-605-7130, dejohnso@umaryland.edu. The CRADA must be consistent with the approved protocol, ICF and HIPAA authorization.